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## **Product Safety - Quality versus Product Space**

To use the words of the late Dylan Thomas “To begin at the beginning...”

Before we can talk about or discuss any subject we must, of course, speak the same language. Within the subjects of Product Safety, Regulatory Compliance and the Low Voltage Directive we use words in special ways, and so the first task of this paper is to explain some of the basics. Here we consider the relationship between product safety and ‘quality’.

There is a general misconception that if I buy from a ‘quality’ company that I will get a fully compliant product.

Whilst this seems quite a reasonable and valid assumption it is, sadly, not wholly correct - let me explain.

If I buy a product with the mark of a European safety agency (such as BSI, TÜV, NEMKO, etc.) I can be reasonably sure that the product was tested, found to be compliant; and that there will be a manufacturing audit of the products (usually) four times a year. What is more I can have the same degree of confidence in this whether the manufacturer is ISO 9000 accredited or not.

This immediately looks wrong because it is natural to expect any company that makes such a significant commitment to quality to produce ‘better’ products: this misunderstanding is essentially because we do not understand the difference between quality systems, ‘quality’, and Quality.

So why is Product Safety compliance outside of quality systems: and what is the difference between quality system and Quality?

More than 2,000 years ago Tao Te Ching wrote “...the quality that can be defined is not Absolute Quality” and “... Quality and its manifestations are in their nature the same...”.

In his book “Lila an inquiry into morals” Robert Pirsig<sup>1</sup> writes: “Quality doesn't have to be defined. You understand it without definition, ahead of definition. Quality is a direct experience independent of and prior to intellectual abstractions.”

This was echoed by Mr. Hiroshi Hamada<sup>2</sup> who expressed his view that:- “Quality is in the heart, it is in the soul, it is in the mind, and it is in the spirit.”

Personally, I would go one stage further than Mr. Hiroshi Hamada and suggest that unless you can *feel* quality then there will be no training course, nor process, on this earth that will help you to achieve it within your company.

If we take this concept ‘on trust’ the ‘fact’ that we have something that we call Quality that we cannot define, understand or know, and that this Quality ‘thing’ is made up of lots of other ‘bits’ that we can define, understand and know. If, for a moment, we accept this concept something rather wonderful happens.

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<sup>1</sup> ISBN 0-552-99504-5 First published 1991

<sup>2</sup> Mr. Hiroshi Hamada is President of Ricoh and spoke at the 1991 EuroPACE Quality Forum.

ISO 9000 and Product Safety can be defined: therefore, according to our hypothesis, they must each form a part of Quality. This is important because it allows us to understand that our quality systems and Product Safety are related - in that they form part of something bigger which we all constantly attempt to quantify but upon which we cannot agree.

If we put this into an everyday context it can explain two of the many odd 'things' that I have experienced.

?? I was looking through some yachting magazines and found an advertisement for a company making anchors. The advert read "quality anchors fully compliant with BS 5750"

?? the sales manager of a company told me that his company's product met and complied with ALL the world-wide safety standards because they had "5750"

Both statements are incorrect: but why?

Simplistically, the quality system can exercise its influence only on the process whereas Product Safety exercises its influence only upon the product.

There is a fundamental difference between Process Space and Product Space - in that the quality process cannot, by itself, change the physical characteristics of a product. The corollary of this is that Product Safety cannot directly affect the quality processes or how they operate within a company.

Thus we can now explain and understand one of the first causes of confusion about the Low Voltage Directive and CE Marking.

To put this into Rudyard Kipling's words:

*I keep six honest serving men (they taught me all I knew);*

*their names are What, and Why and When, and How and Where, and Who.*

Our company quality plan will show and define the *Who, How, Why, Where* and *When*.

It is our Product Safety plan that will define the *What* issues, the physical characteristics of our products; and it will do this without any regard for the processes that bring the products into being. If it does attempt to cross this boundary then there is a risk that its purpose will become confused and diluted.

However there is a link between these two. Product Safety, being another facet of Quality, will identify parts of its 'brother', the quality process, what processes may need to change so that all manufactured items comply with the product (safety) standard.

If we take our new-found knowledge of the differences between product-space and process-space then we can conclude that the processes operating within a quality assessed company will ensure that all of its production will be uniformly compliant - or, in the worst case scenario, all of the products will be non-compliant.

This may all seem like an exercise in 'splitting hairs' and semantics but these concepts are the very foundations of what we must achieve and I make do apology for labouring them. I shall now explain why they are important - after which it may be useful to reread above.

**The vast majority of products<sup>3</sup> that have not been properly assessed for product safety compliance will fail to comply with their appropriate safety standard.**

This state of affairs seems constant and is not just a UK shortcoming. Let me substantiate these statements.

At very recent exhibition in London I was amazed at the amount of CE Marked and non-compliant equipment that had been put on public display. Some of the non-compliances included an incorrect "CE" mark; incorrect rating and product labelling; unreliable earthing; assess to Basic Insulation; Accessible parts that could become "Live"; and accessible hazardous voltages. Together they covered the full range of hazards, from 'the trivial' to 'the potentially dangerous'.

Whilst these findings were of no particular surprise to me: I was alarmed by the unresponsive reaction from some of the exhibitors: I had expected some reaction: in some cases there was none whatever - in a few there was a tacit acceptance of the situation. I believe that we ALL have a duty to change this attitude.

In contrast, last year about 50% of my company's business was overseas - with companies that are intent to penetrate our European markets and were taking the necessary steps to put appropriate training in place. This year my company received enquiries from 37 countries following the launch of a CD-ROM on electrical safety; to date overseas sales are greater than UK and European sales.

The conclusion that I draw is that the EU is no better or worse in terms of Low Voltage Directive compliance than is our international competition: but it is they who have the commitment and will eventually, if unchallenged, beat us in our own marketplace.

So what do I do now? Answering the following questions may be a good start to help determine if your company has the fundamental steps in place to produce compliant products, consistently:-

1. What harmonised standard is appropriate to your products?
2. Do your designers have a 'personal' copy?
3. Do you have a product safety review check-list?
4. Does it mirror the safety standard on a clause by clause basis?
5. Do the safety test results include Abnormal Conditions of test?
6. Have you defined the safety critical features and aspects of the product?
7. Does your quality process verify these features during manufacturing audits?

If you are unsure of any of these questions, or do not know the answer to any of them, there are two further questions to consider:-

1. Do my products conform to the Low Voltage Directive?
2. How can I demonstrate Due Diligence?

We will go on to consider these, and other questions at another time.....

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<sup>3</sup> A major test house has stated publicly that 100% of all new products submitted for testing failed to comply with the required standard.